K021791 p1/1

AUG 26 2002

CONFIDENTIAL

VERTE-STACK™ Spinal System
510(k) Summary
May 2002

I. **Company:** **Medtronic Sofamor Danek**
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

II. **Proprietary Trade Name: VERTE-STACK™ Spinal System**

III. **Product Description**

The VERTE-STACK™ device, is a stackable PEEK spacer, which inserts between vertebral bodies in the anterior thoracic and lumbar spine. The device is intended for vertebral body replacement to aid in the surgical correction and stabilization of the spine. The construct is not intended to be employed as a stand-alone device. The VERTE-STACK™ device is fabricated and manufactured from POLYETHERETHERKETONE (PEEK OPTIMA LT) as described by ASTM F-1579. The Tantalum marker used for this product is made to the voluntary standard of ASTM F-560. The VERTE-SPAN™ components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

The VERTE-STACK™ Spinal System must be used with additional anterior and/or posterior spinal instrumentation to augment stability

IV. **Indications**

The VERTE-STACK™ Spinal System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The VERTE-STACK™ Spinal System is to be used with supplemental fixation. Specifically, the VERTE-STACK™ device is to be used with the Medtronic Sofamor Danek ZPLATE II Anterior Fixation System, Titanium DYNALOK™ CLASSIC Spinal System, Laurain DeWald Anterior Fixation System, Titanium TSRH® Spinal System, Titanium CD HORIZON® Spinal System, the Titanium GDLH® Spinal System or their successors. Additionally, the VERTE-STACK™ device is intended to be used with bone graft.

V. **Substantial Equivalence**

Documentation was provided which demonstrated the VERTE-STACK™ Spinal System to be substantially equivalent to the previously cleared VERTE-SPAN™ Spinal System (K010930), the DePuy AcroMed Stackable Cage System (K001340) the OEC/Rezaian Spinal Fixator (K841189), the Osteotech Vertebral Body Replacement device (K012254), and the PYRAMESH®-C Implant System (K011406) in terms of its size, indications for use and use with supplemental fixation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 26 2002

Richard W. Treharne, Ph.D.
Senior Vice President, Research and Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K021791
Trade/Device Name: VERTE-STACK™ Spinal System
Regulatory Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: May 30, 2002
Received: May 31, 2002

Dear Dr. Treharne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

May 2002

510(k) Number (if known): K021791

Device Name: VERTE-STACK™ Spinal System

Indications for Use:

The VERTE-STACK™ Spinal System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The VERTE-STACK™ Spinal System is to be used with supplemental fixation. Specifically, the VERTE-STACK™ device is to be used with the Medtronic Sofamor Danek ZPLATE II Anterior Fixation System, Titanium DYNALOK™ CLASSIC Spinal System, Laurain DeWald Anterior Fixation System, Titanium TSRH® Spinal System, Titanium CD HORIZON® Spinal System, the Titanium GDLH® Spinal System, or their successors. Additionally, the VERTE-STACK™ device is intended to be used with bone graft.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional 1-2-96)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021791